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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | | ATTORNEY DOCKET NO. |
|---|---|---|---|---|
| 09/648,858 | 08/25/00 | DITTGEN | M | 388A |

HM12/0307

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| EXAMINER | |
|---|---|
| BAHAR,M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1617 | 3 |

**DATE MAILED:** 03/07/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/648,858 | DITTGEN ET AL. | |
| | Examiner | Art Unit | |
| | Mojdeh Bahar | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-14* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a combination preparation (composition) and a method of administering said combination preparation comprising from 2 to 4 first stage daily dosage portions each including an effective amount of at least one natural estrogen as sole active ingredient, from 16 to 22 second stage daily dosage portions each including an effective amount of a combination of at least one natural estrogen and at least one natural or synthetic gestogen as active ingredient, from 2 to 4 third stage daily dosage portions each including an effective amount of at least one natural estrogen as sole active ingredient; and from 2 to 4 additional stage daily dosage portions each containing a pharmaceutically acceptable placebo, classified in class 514, subclasses 170 and 178, for example.

II. Claims 8-14, drawn to a combination preparation and a method of administering said combination preparation for contraception comprising a first stage consisting of from 2 to 4 first stage daily dosage portions, a second stage consisting of two groups of second stage daily dosage portions, a third stage consisting of from 2 to 4 additional stage daily dosage portions; wherein said first stage daily dosage portions each consist of an effective amount of at least one natural estrogen, said second stage daily dosage portions of said first group and said second group each consist of an effective amount of a combination of said at least one natural estrogen and at least one natural or synthetic gestogen, said third stage daily dosage portions each consist of an effective amount of said at least one natural

estrogen and said additional stage daily dosage portions each consist of a pharmaceutically acceptable placebo; wherein said first group of said second stage consists of 3 to 5 of said second stage daily dosage portions, said second group of said second stage consists of 13 to 17 of said second stage daily dosage portions and said second stage daily dosage portions each include more of said at least one synthetic or natural gestogen in said second group than in said first group; and wherein said effective amount of said at least one natural estrogen is constant in said first stage and also constant in said third stage but said effective amount in said third stage is smaller than said effective amount in said first stage, classified in class 514, subclasses 170 and 178, for example,

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The method of administering the combination preparation in Group I and hence its mode of operation is different than the method of administering the combination preparation in Group II. In Group I the second administration stage(designated as part b) ) consists of administering daily for 16 to 22 days an effective amount of at least one natural estrogen and at least one natural or synthetic gestogen as active contraceptive ingredient in a second administration stage. In Group II, the second stage consists of two groups of second stage daily dosage portions wherein said second stage daily dosage portions of said first group and said second group each consist of an effective amount of a combination of said at least one natural estrogen and at least one natural or synthetic gestogen,

wherein said first group of said second stage consists of 3 to 5 of said second stage daily dosage portions, said second group of said second stage consists of 13 to 17 of said second stage daily dosage portions and said second stage daily dosage portions each include more of said at least one synthetic or natural gestogen in said second group than in said first group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
March 5, 2001

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600